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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,865	02/07/2005	Hideko Kosaka	10921.0278USWO	1872

52835 7590 01/21/2011

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EXAMINER	
GERIDO, DWAN A	
ART UNIT	PAPER NUMBER
1777	
MAIL DATE	DELIVERY MODE
01/21/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/523,865	KOSAKA, HIDEKO	
	Examiner	Art Unit	
	Dwan A. Gerido, Ph.D.	1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 13, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Proffit et al., (US 2005/0106748) in view of Corey et al., (US 5,187,104) alone, or in further view of Lau (EP 0,361,244).

4. Regarding claims 1 and 20, Proffit et al., teach a method (examples 5 and 6), indicator (paragraph 0038), and test piece (paragraph 0027) for assaying albumin (paragraphs 0092, 0097) in a urine sample (paragraphs 0050, 0101). Proffit et al., do not explicitly teach measuring albumin with the claimed compounds; however, Proffit et al., do teach phloxine B which is identical to compounds (1)-1, (2)-1, and (3)-1 as a suitable indicator for the assay (paragraph 0038). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the teachings of Proffit et al., wherein phloxine B is used as an

indicator determining albumin concentration in a urine sample as taught by Proffit et al. Proffit et al., do not teach measuring an albumin concentration ranging from 10-20mg/dL.

Corey et al., teach test strips for assaying urinary albumin wherein the test strip comprises polypropylene glycol (column 8 lines 28-37, 68 – column 9 line 5), and is capable of detecting albumin in a concentration ranging from 2 to 500mg/dL (column 6 lines 3-5). Corey et al., teach that utilizing polypropylene glycol provides the advantage of developing more color at a faster rate, and better resolution between albumin levels. Corey et al., also teach that it is advantageous to measure albumin in a range of 2 to 500mg/dL in order to provide early detection of life threatening pathologies (column 6 lines 8-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffit et al., in view of Corey et al., to utilize polypropylene glycol as a sensitizer, and to measure albumin in a concentration ranging from 2 to 500mg/dL in order to increase the kinetics of the albumin response, generate better resolution between albumin levels, and to provide early detection of life threatening pathologies as taught by Corey et al.

Furthermore, Lau teaches a method of assaying urine albumin wherein the normal concentration of albumin ranges from 10-20 mg/dL (page 7 lines 48-54). Lau further teaches that protein concentrations below 10 mg/dL and above 20 mg/dL are indicative of a protein deficiency and/or disease states (page 7 lines 48-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Proffit et al., in view of Corey et al., in further view of Lau to measure albumin in the range of 10-20 mg/dL in order to determine whether a subject exhibits a normal albumin concentration in urine as taught by Lau.

Response to Arguments

5. Applicant's arguments with respect to claims 1, 13, 19, and 20 have been considered but are moot in view of the new ground(s) of rejection.

6. At the outset, the Examiner acknowledges the amendments to claims 1, 13, and 19, the addition of new claim 20, and the cancellation of claims 7, 8, and 18. Applicant has amended the claims to recite a method and test piece for assaying urinary albumin in a concentration range of 10-20mg/dL, and a sensitizer that increases the coloration sensitivity of the assay indicator. The Examiner has rejected claim 1 as being obvious of Proffit et al., in view of Corey et al, or Proffit et al., in view of Corey et al., and further in view of Lau. Reference to Proffit et al., is cited for teaching measuring urinary albumin wherein phloxine B is utilized as a protein assay indicator. The Examiner concedes that Proffit et al., do not explicitly teach the limitations regarding the change in color, but asserts that these features are inherent in the teachings of Proffit et al., as Applicant does not provide any evidence to show that the claimed color change is specific and/or unique to the instant application. The Examiner also concedes that reference to Proffit et al., do not albumin a concentration range of 10-20mg/dL, and a sensitizer for increasing the coloration sensitivity of the indicator.

Reference to Corey et al., is cited for teaching a test strip comprising polypropylene glycol as a sensitizer, and for teaching measuring albumin in a concentration range of 2 to 500mg/dL. With respect to the sensitizer, Corey et al., teach that polypropylene glycol increases the kinetics for the albumin response, and produces better resolution between albumin levels thereby providing sufficient motivation to combine the references. With respect to the concentration range, Corey et al., teach that measuring albumin in concentrations ranging from 2

to 500mg/dL allows for early detection of potentially life threatening diseases. Given the teachings of Proffit et al., in view of Corey et al., it is the Examiner's position that the limitations of the instant claims are taught by the combination of references. However, if one were to construe 2-500mg/dL as too large of a concentration range, the Examiner has also cited reference to Lau which teaches measuring urinary albumin wherein the normal concentration range is between 10 and 20mg/dL. Lau teaches that concentrations below 10 and above 20mg/dL are indicators for disease states thereby providing sufficient motivation to combine the references. Therefore, in light of the teachings of the prior art, and the arguments presented here, the rejection of claims 1, 13, 19, and 20 are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAG

/ROBERT J. HILL, JR/
Primary Examiner, Art Unit 1700